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International Bureau

INTERNATIONAL APPLICATION PUBLISHED UNDER THE PATENT COOPERATION TREATY (PCT)

(51) International Patent Classification 6 : A61M 3/00, 3/02, 25/00 — A1

(11) International Publication Number: **WO 97/35629**

(43) International Publication Date: 2 October 1997 (02.10.97)

(21) International Application Number: PCT/US97/04885

(22) International Filing Date: 26 March 1997 (26.03.97)

(30) Priority Data:
8/69562 26 March 1996 (26.03.96) JP

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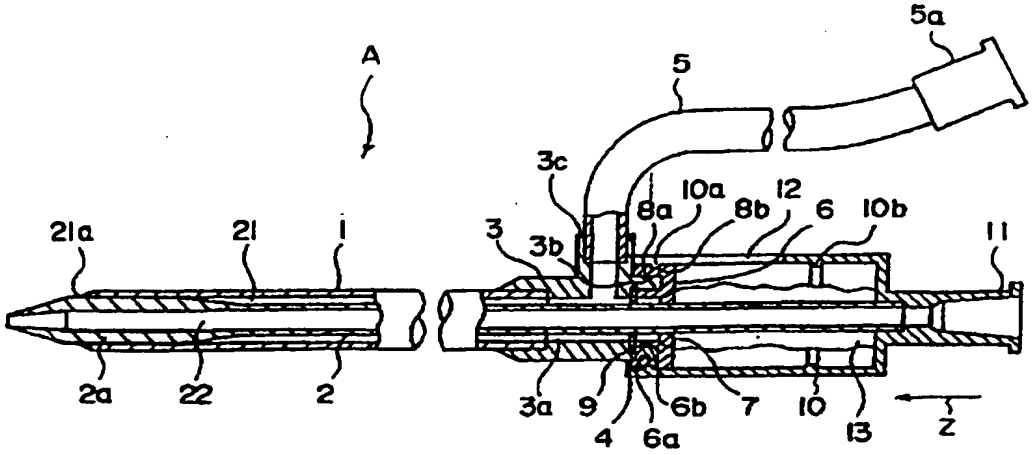
(81) Designated States: AL, AM, AT, AU, AZ, BA, BB, BG, BR, BY, CA, CH, CN, CU, CZ, DE, DK, EE, ES, FI, GB, GE, HU, IL, IS, JP, KE, KG, KP, KR, KZ, LC, LK, LR, LS, LT, LU, LV, MD, MG, MK, MN, MW, MX, NO, NZ, PL, PT, RO, RU, SD, SE, SG, SI, SK, TJ, TM, TR, TT, UA, UG, US, UZ, VN, ARIPO patent (GH, KE, LS, MW, SD, SZ, UG), Eurasian patent (AM, AZ, BY, KG, KZ, MD, RU, TJ, TM), European patent (AT, BE, CH, DE, DK, ES, FI, FR, GB, GR, IE, IT, LU, MC, NL, PT, SE), OAPI patent (BF, BJ, CF, CG, CI, CM, GA, GN, ML, MR, NE, SN, TD, TG).

Published
With international search report.

(54) **Title:** DOUBLE LUMEN CATHETER



(57) **Abstract**

The double lumen catheter consists of a blood with drawing lumen (21) between the outer tube (1) and the inner tube (2) with the expanded leading end, and a blood injecting lumen (22) which is the inner lumen of the inner tube (2). A blood withdrawing lumen is branched and extended (3c) near the base of the outer tube (1) and a seal valve (9) is installed on the base side of the outer tube (1) adjacent to the branch. The seal valve (9) seals the blood withdrawing lumen (21) but also allows the inner tube (2) to slide through it freely. A blood injector connector (11) is installed at the base of the inner tube (2). A nearly cylindrical position holder (10) equipped with stoppers (10a) and (10b) on the inner circumference is formed as a unit body with the blood injector connector (11) at its one end. When the engaging piece (8b) of the position setter (6) is engaged with the stopper (10b) installed on the base side of the position holder (10), the expanded end (2a) is pushed out from the outer tube (1) and the opening (21a) of the blood withdrawing lumen is formed between the inner tube (2) and the leading end of the outer tube (1). When, on the other hand, the engaging piece (8b) is engaged with the stopper (10a) installed on the opening side, the expanded end (2a) is retracted in the outer tube (2) and closes the end opening (21a) of the blood withdrawing lumen.

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DOUBLE LUMEN CATHETER

TECHNICAL FIELD

1. Field of the Invention

This invention has to do with double lumen (double tube-shaped) catheters used for dialysis treatment, etc., and, more particularly has to do with a structure for double lumen catheters that is particularly effective when a heparin lock is maintained within the blood vessel while dialysis is not being performed.

2. Description of the Prior Art

The invention disclosed in patent disclosure Hei 1-303159, shown in Figure 11, is an example of a double lumen catheter for circulation of blood outside of the body, where the catheter remains within the blood vessel.

The double lumen catheter disclosed in patent disclosure Hei 1-303159 (Conventional Example 1) is structured, as shown in Figure 11 (a), from a No. 1 inner lumen that has multiple side holes 51a in the tip part, and which is formed in the vicinity of the tip part from the base part of a catheter 50, a No. 2 inner lumen 52 that has multiple side holes 52a in its tip part and that passes through from the base of catheter 50 through to the tip part, and a connection tube that is equipped at the base (not shown). Moreover, as is shown in Figure 11 (b) the No. 1 inner catheter 51 is formed in a shape that, in cross section, is nearly semicircular, and No. 2 inner catheter 52 is formed in a shape that, in cross-section, is nearly semicircular meeting with the part that is formed by No. 1 inner catheter 51, so that the tip part side forms a part that, in cross-section, is circular.

Moreover, after the double lumen catheter 50 is secured within the blood vessel using guide wires, etc., the tube that connects to the No. 1 inner lumen 51 is connected to the blood removal-side of the dialysis circuit, and the tube that is connected to the No. 2 inner lumen 52 is connected to the blood delivery-side of th dialysis circuit to begin circulation outsid of the body, at which time the blood flows from the side holes 51a of the No. 1 inner lumen 51 into the inside of

No. 1 inner lumen 51, and is s nt to the dialysis circuit, and the blood from th dialysis circuit is sent through No. 2 inner lumen 52 into the blood vessel from side holes 52a.

After completing the circulation outside of the body, then when double lumen catheter 50 remains within the blood vessel, both inner lumens 51 and 52 are flushed with a sanitary saline solution to which heparin is added to perform a heparin lock so that blood clots will not form where the blood flows within said No. 1 inner lumen 51 and said No. 2 inner lumen 52.

Moreover, Figure 12 is a structural cross-sectional diagram of required parts for another conventional double lumen catheter and a n-n cross-sectional diagram thereof, where this double lumen catheter 53 (Conventional Example 2) is structured from an integrated outer catheter 54 having side holes 54a at its tip, and inner catheter 55 that passes through the inside of outer catheter 54 where its tip part extends from the tip of outer catheter 54, where the connecting tubes (not shown) of both catheters 54 and 55 are integrated together.

The double lumen catheter 50, described above, is similar to the double lumen catheter 53 having this structure, in that it is secured within a blood vessel and the respective connecting tubes are connected to a dialysis circuit to perform circulation outside of the body, moreover, after the circulation outside of the body is complete, the insides of both catheters 54 and 55 are flushed with a sanitary saline solution to which has been added heparin to perform a heparin lock.

DISCLOSURE OF INVENTION

When the double lumen catheter 50 of the Conventional Example 1, described above, is left within the blood vessel during times when dialysis is not performed, blood flows into said No. 1 inner lumen 51 and said No. 2 inner lumen 52, and thus to prevent the formation of blood clots, both inner lumens 51 and 52 are flushed with sanitary saline solutions, to which heparin has been added, to perform a heparin lock. However, because multiple side holes 51a and 52a are equipped in the tips of said No. inner lumen 51 and No. 2 inner lum n 52, respectively, th sanitary saline solution to which heparin has be n added within both inner lumens 51 and 52 rapidly flows into the blood vessel side from

the side holes 51a and 52a and is gone, so that, conversely, blood flows into both inner lumens 51 and 52, so that blood clots are formed. Because of this, there are problems such that the next time that circulation outside of the body is performed, blood flow cannot be obtained because of the blood clots in both inner lumens 51 and 52 or that only a small blood flow can be obtained.

Moreover, in the double lumen catheter 53 of Conventional Example 2, there are no side holes 54 in inner catheter 55, and thus it is difficult for the sanitary saline solution to which heparin has been added within inner catheter 55 to escape into the blood vessel side; however, because the sanitary saline solution to which heparin has been added within the outer catheter 54 escapes in a short period of time into the blood vessel side through the multiple side holes 54a, as it did in Conventional Example 1, blood flows into the outer catheter 54 and blood clots form, presenting obstacles for the next time when there is circulation outside of the body.

With that, a structure has been conceived of to solve the problems described above with a separate double lumen catheter outer catheter and inner catheter, where the inner catheter is withdrawn from the outer catheter during non-dialysis times and the inside of the outer catheter is flushed with the sanitary saline heparin solution, so that the inside of the outer catheter is filled with either a hollow or solid obturator where the side wall of this obturator blocks the holes in the outer catheter, thus preventing the formation of blood clots within the outer catheter. However, because in this double lumen catheter, whenever the double lumen catheter is left within the blood vessel during non-dialysis times, it is necessary to withdraw the inner catheter from the outer catheter and to replace it by inserting the obturator, the operations both take time and place a heavy load on the doctor, along with potentially damaging the patient by making it likely for the patient to bleed during the substitution. Moreover, from a hygiene perspective as well, it was necessary to use a new inner catheter and obturator whenever the substitution was performed, leading to problems of being uneconomical.

This invention solves the problems described above, by maintaining for extended periods of time the heparin lock that solidly prevents the flow of blood from the blood vessel into the catheter during the time of the heparin lock, for the

purpos s of providing a doubl lumen catheter that is economical and easy to use and that reduces th load on both th patient and the doctor.

The double lumen catheter in this invention is equipped with at least a double lumen formed from a blood removal lumen, which is a lumen that is formed between an outer tube, wherein the tip part outer radius is reduced, and an inner tube, wherein the outer diameter of the inner tube is smaller than the inner diameter of the aforementioned outer tube, and where the tip portion of the inner tube is equipped with a wide diameter part wherein the outer diameter of the tip part of the inner tube is nearly the same as the inner diameter of the tip part of the outer tube, and a blood delivery lumen, which is the inner lumen of the inner tube, where the blood removal lumen is equipped with a blood removal tube that extends in a branch from the blood removal lumen near the base of the outer tube, and equipped with a seal valve unit that seals the blood removal lumen at the base side near the branch part of the outer tube and that can cause the inner tube to slide freely.

Moreover, the double lumen catheter of this invention is equipped with a freely constricting sleeve that tightly covers and seals the inner tube and which is located within the position securing means between base part side of the position securing means and the base of the position determination part along with having a position securing means that is nearly tube shaped and which is equipped with connect stop parts in at least 2 locations on the inner peripheral surface which are formed as a single unit at one end of a blood delivery-side connector where the blood delivery-side connector is equipped at the base part of the inner tube, and a position determination part that slides freely within the position-securing means and which can slide freely into the inner tube, and which is equipped with a connection part stopped by the connection stop part of the position securing means at the outer peripheral surface.

Moreover, the double lumen catheter of this invention is structured so that not only is a blood removal lumen tip opening part formed between the inner tube and the outer tube tip part by the wide diameter part extending out from the outer tube when the connection part position determination part is stopp d at the connection stop part quipp d on the base side of the position securing part, but also that the wide diameter part blocks the blood removal lumen tip part opening

by being placed in the outer tube when the position determination part of the connection part is stopped at the connection stop part that is quipped at the opening part side at the other nd of th position securing part.

The double lumen catheter of this invention is structured with the side wall of the tip part of the outer tube and/or the side wall of the wide diameter part being equipped with at least one side hole, and structured so that when the wide diameter part is positioned within the outer tube, the side holes in the outer tube tip part and/or the side holes in the wide diameter part are positioned so that the side wall of the outer tube and/or the side wall of the wide diameter part block the side holes, and structured so that when the connector part of the position determination part is positioned at the stop part at the base side of the position securing means, then the wide diameter part extends from the outer tube and a blood removal tip opening is formed between the inner tube and the outer tube tip part, or the wide diameter part opens the outer tube tip part side holes and wide diameter part high side holes without extending out of the outer tube, and when the position determination means connection part is stopped at the stop part equipped on the opening side of the position securing means, the wide diameter part blocks the outer tube side holes and the wide diameter part side holes and the blood removal lumen tip opening part.

Moreover the double lumen catheter of this invention is equipped with a stylet, which is equipped with a plunger at its base, that can easily fit into the blood delivery lumen of the inner tube so that the tip part extends from the tip part of the outer tube and its outer wall forms a tight seal with at least the inner wall of the tip part of the inner tube.

Furthermore the double lumen catheter of this invention is structured so that the inner diameter of the tip part of the outer tube is of an smaller diameter, or so that the reduced diameter part is made from elastic materials.

The double lumen catheter of this invention is such that the inner walls of the inner tube being structured from materials that are hard while along with the outer wall of the inner tube being structured from materials that have relatively good compatibility with the wide diameter part where the inner tube is structured in an outer wall and inn r wall double-layer structur such that the larg diamet r part is made from a soft material, metal wires being embedded within

the inner wall of the inn r tube, and/or th wide diam ter part being structured from an elastic material.

Moreover, the double lumen catheter of this invention is equipped with a slit at the tip of the inner tube, where the tip of the inner tube is structured in a form where the most leading edge of the tip is blocked.

By sliding in the axial direction the inner tube, which is equipped with a wide diameter part at its tip end in this way, it is possible to place the wide diameter part within the outer tube to close the blood removal lumen tip opening, the side openings within the wide diameter part, and the side openings within the outer tube tip part, blocking them with the side wall of the outer tube and with th side wall of the wide diameter part, thereby preventing blood from flowing into the blood removal lumen and the blood delivery lumen during heparin lock.

Moreover, by inserting the stylet into the blood delivery lumen of the inner tube or by closing the leading tip of the inner tube and then equipping that part with a stylet, or by reducing the inner diameter of the tip part of the outer tube and by structuring the reduced diameter part from an elastic material, it is not only possible to make it easy to insert the double lumen catheter into the blood vessel, but it also possible to prevent the flow of blood into the blood removal lumen and the blood delivery lumen during heparin lock.

Moreover, by structuring the inner tube from a material that is hard or by embedding metal wires into the wall of the inner tube, or by structuring the wide diameter part from an elastic material, damage to the blood vessel from the wide diameter part can be prevented easily by maintaining torque transmission while suppressing twisting of the inner tube.

BRIEF DESCRIPTION OF DRAWINGS

Figure 1 is a structural diagram showing the first form of embodiment of this invention.

Figure 2 is an operational diagram showing the first form of embodiment of this invention.

Figure 3 is a structural diagram showing the second form of embodiment of this inv ntion and an operational xplanation diagram of the important parts.

Figure 4 is a structural diagram showing the third form of mbodiment of

this invention.

Figure 5 is a structural diagram showing the fourth form of embodiment of this invention.

Figure 6 is a structural diagram showing the fifth form of embodiment of this invention.

Figure 7 is an expanded cross-sectional diagram showing the important parts of the sixth form of embodiment of this invention.

Figure 8 is an expanded cross-sectional diagram of an example where the inner tube is changed in the sixth form of embodiment of this invention.

Figure 9 is an expanded cross-sectional diagram showing the important parts of the seventh form of embodiment of this invention.

Figure 10 is an expanded cross-sectional diagram of the outer tube related to the first form of embodiment of this invention, and a cross-sectional diagram of a modified example thereof.

Figure 11 is a structural diagram and an n-n cross-sectional diagram of the structure of a conventional double lumen catheter

Figure 12 is a structural cross-sectional diagram and an n-n cross-sectional diagram showing the important parts of another conventional double lumen catheter.

MODE FOR CARRYING OUT THE INVENTION

Embodiment Form 1

Figure 1 is a structural diagram of the first form of embodiment of this invention. In this figure, 1 is the outer tube wherein the outer diameter of the tip part of the tube is reduced, 2 is the inner tube which has an outer diameter that is less than the inner diameter of outer tube 1, where the inner tube is equipped with a wide diameter part 2a that has an increased outer diameter so that it is about the same as the inner diameter of outer tube 1 at its tip part and which also has a reduced outer diameter at its leading side, where blood removal lumen 21 is a lumen which is formed between outer tube 1 and inner tube 2 and which passes through the inside of outer tube 1, and blood supply lumen 22 is the inner lumen of the inner tube to form a double lumen structure. 3 is a support tube wher the tip thereof is rigidly fixed to the base of outer tube 1 wher inner

lumen 3a passes through blood removal lumen 21, a concave part 4 is equipped on the center part of the bas side, and connecting concave part 3 is equipped on the outer peripheral surface of the base part. Moreover, on the side wall near the base part of this support tube 3 (or in this case, at the top part of the side wall), there is a blood removal-side connector 5a where blood removal tube 3c to which is connected blood removal-side tube 5 which is connected to inner lumen 3a is branched.

6 is a position determination means formed in a double circular tube shape with inner wall 6a equipped concentrically with outer wall 6a, and which is equipped with a through hole 7 wherein inner tube 2 can slide freely at its core, stop convex part 8a, which stops connector concave part 3b which is equipped in the outer peripheral surface of the base of support tube 3, is equipped on the inner peripheral surface of outer wall 6a, connection concave part 8b is equipped on the outer peripheral surface of outer wall 6a, inner wall 6b fits into the concave part 4 of support tube 3, and the connection stop part 8a of outer wall 6a is stopped by connection concave part 3b of support tube 3 to connect the position determination means 6 to the base of support tube 3. 9 is a ring-shaped seal valve which seals the blood removal lumen 21 that is attached to the lower part of concave part 4 of the support tube 3 and in which its inner periphery is in sliding contact with the outer periphery of inner tube 2, and which is fastened by inner wall 6b of position determination means 6 that is inserted into the concave part 4 of support tube 3, structured, for example, of a silicone rubber or another elastic material.

10 is a position fastening means that is tube shaped and that has blood delivery-side connector 11 on one end and that is open on the other end, where the base part of inner tube 2 is fastened at the tip part of blood delivery-side connector 11, where this inner tube 2 and the position securing means 10 are fabricated as a single unit. Moreover, the inner wall of the opening side of this position securing method 10 is equipped with a stop connection convex part 10a that stops at the connection concave part 8b equipped on the outer peripheral surface of outer wall 6a or position determination material 6, where, similarly, the bas sid is also equipped with conn ction stop conv x part 10b, and where the side wall on the opening part side (or in this case, the top portion of the sid

wall) is equipped with a nearly U shaped guide hole 12 that guid s blood removal tube 3c of support tube 3. 13 is a sterile support sleeve that can be freely extended and retracted and that tightly covers inner tube 2 positioned at location securing means 10, and which is equipped between the base of the position determination part 6 and the inside of the base of position determination part 10, made from, for example, a thin transparent film such as polyethylene.

Moreover, outer tube 1, inner tube 2, support tube 3, blood removal-side tube 5, position determination part 6, and position securing part 10 are all made, for example, from a synthetic resin material such as polyurethane to form the double lumen catheter "A" that will be used in circulation outside of the body.

In the example of embodiment of this structure, as shown in Figure 1, the double lumen catheter A is inserted into a blood vessel using a guide wire, etc., and is fastened there when it is in a state where the connection stop convex part 10a of the opening side of the position securing means 10 is stopped at the connection concave part 8b of the position determination part 6, or in other words, is in a state where the wide diameter part 2a of the inner tube 2 is positioned inside of outer tube 1. Consequently, blood removal-side tube 5 is connected to the blood removal-side of the dialysis circuit through connector 5a, and position securing means 10 [SIC?] is connected to the blood supply-side of the dialysis circuit through connector 11. Next, when the connection of connection stop convex part 10a of the open part side of position securing means 10 and the connection concave part 8b of position determination part 6 is released, position securing means 10 is slid in the forward direction (in the direction marked with arrow Z shown in Figure 1), and connection stop convex part 10b of the base side of position securing means 10 is stopped at the connection concave part 8b of position determination part 6. At the same time, the inner tube 2 also moves in the forward direction, and as shown in Figure 2, the wide diameter part 2a of inner tube a extends out from the tip part of outer tube 1a to create a blood removal lumen tip opening part 21a between inner tube 2 and the tip part of outer tube 1. Moreover, the sterile support sleeve 13 is compressed by the movement of the position determination part 6, and is maintain d in that state within the inside of p sition securing means 10.

When the circulation outside of the body begins, the blood within the

blood vessel flows into blood removal lumen 21 from blood removal lumen tip opening 21a formed between inner tube 2 and the tip part of outer tube 1, as shown by the arrow labeled X in Figure 2, and is sent to the dialysis circuit through inner lumen 3a of support tube 3, blood removal tube 3c, and blood removal-side tube 5. Moreover, the blood from the dialysis circuit, as is shown by the arrow labeled Y in Figure 2, is delivered to the blood vessel from the tip part of inner tube 2 (blood delivery lumen 22) through blood delivery lumen 22 which is the inner lumen of inner tube 2.

When the circulation outside of the body is complete, if the double lumen catheter A is left within the blood vessel, then the dialysis circuit is removed from blood removal-side connector 5a and blood delivery-side connector 11, and blood supply lumen 22 of inner tube 2 is flushed with a sanitary saline heparin solution from the blood supply-side connector 11. Then the blood removal lumen 21 is flushed with the sanitary saline heparin solution through blood removal-side tube 5, etc., from the blood removal-side connector 5a side, to perform a heparin lock on blood removal lumen 21 and blood supply lumen 22. Moreover, after the blood supply-side connector 11 is blocked by inserting a rubber stopper, etc. (not shown), then when the connection of the connection stop convex part 10b of the base side of position securing means 10 and the connection concave part 8b of position determination part 6 is released, the position securing means 10 is slid in the backwards direction (the direction opposite to the direction shown by the arrow labeled Z in Figure 1), and connection stop convex part 10a of the opening part side of connection securing means 10 is stopped at the connection concave part 8b of the position determination part 6. At the same time, the inner tube 2 is also moved in the backwards direction, so as shown in Figure 1 the blood removal lumen tip opening part 21a is closed by the wide diameter part 2a being positioned inside of outer tube 1, which prevents the sanitary saline heparin solution within blood removal lumen 21 from escaping into the blood vessel side from blood removal lumen tip opening part 21a. Moreover, the sterile maintenance sleeve 13 extends with the sliding movement of the position determination part 6 to return to the form shown in Figure 1. Furthermor , in the inner tube 2, the inner diameter of the tip part, or in other words the lumen diameter of blood delivery lumen 22, is

fabricated with a size that makes it difficult for the sanitary saline heparin solution to escape, and thus most of the sanitary saline heparin solution does not escape into the blood vessel side, and so there is no danger of the blood supply lumen 22 becoming blocked by blood clots.

When the circulation outside of the body is to be started again, the position securing means 10 is slid in the forward direction, the connection stop convex part 10b of the base side of position securing means 10 is stopped at the connection concave part 8b of position determination part 6, and the wide diameter part 2a of the inner tube 2 extends out from the tip part of outer tube 1. Then the blood removal lumen 21 and the blood supply lumen 22 are flushed with the sanitary saline heparin solution, blood removal-side connector 5a and blood supply-side connector 11a are connected to their respective dialysis circuit connections, and circulation outside of the body resumes.

In this way, it is possible to open and close the blood removal lumen tip opening part 21a by the wide diameter part 2a of inner tube 2 through sliding position securing means 10 in the axial direction, using connection stop convex parts 10a and 10b of position securing means 10 and connection concave part 8b of position determination part 6 to easily and certainly extend and retract wide diameter part 2a, thus making it possible to support a heparin lock of blood removal lumen 21 for an extended time period while double lumen catheter A is secured within the blood vessel, thus preventing the inadequate blood removal flow and preventing situations where circulation is not possible when circulation outside of the body is restarted because obstructing blood clots in blood removal lumen 21. Furthermore, because it is possible to restart circulation outside of the body with simple operations, the load on both the patient and the doctor is lightened, making it possible to obtain the easily used double lumen catheter A.

Form of Embodiment 2

Figure 3 shows a structural diagram of the second form of embodiment of this invention along with an operational explanation diagram of its important parts. This form of mbodiment has multiple side holes 1a for blood removal connected to blood r moval lumen 21 at the tip part of outer tube 1 found in the first form of embodiment.

Even in this form of embodiment structured in this way, the operation is the same as was explained in the first form of embodiment in that the double lumen catheter B is inserted into the blood vessel using a guide wire, etc., and then is secured there (see Figure 3(a)) when it is in a state where connection stop convex part 10a of the opening part side of position securing means 10 is stopped at the connection concave part 8b of position determination part 6. Following this, blood removal-side connector 5a and blood supply-side connector 11 are connected to their respective dialysis circuits, position securing means 10 is slid in the forward direction so that connection stop convex part 10b of the base part side of position securing means 10 is caused to stop at the connection concave part 8a of the position determination part 6, causing the wide diameter part 2a of inner tube 2 to extend out from the tip part of outer tube 1. At this time, the wide diameter part 2a of inner tube 2, as is shown in Figure 3 (b) does not extend completely out of the tip part of outer tube 1, but rather the blood removal lumen tip opening part 21a is blocked by the wide diameter part 2a of inner tube 2, so the blood is removed only through side holes 1a in outer tube 1. Furthermore, when circulation outside of the body is started, the blood flows into blood removal lumen 21 from side holes 1a of outer tube 1 and is delivered to the dialysis circuit, and blood from the dialysis circuit is delivered to the blood vessel through blood delivery lumen 22 from its tip part.

After the circulation outside of the body is complete, then in the case where the double lumen catheter B will remain within the blood vessel, the blood removal-side connector 5a and blood supply-side connector 11 are removed from the dialysis circuit, blood removal lumen 21 and blood supply lumen 22 are flushed with the sanitary saline heparin solution, and a heparin lock is performed. Next the position securing means 10 is slid in the backwards direction to cause the connection stop convex part 10a of the opening part side of position securing means 10 to stop at the connection concave part 8b of the position determination part 6, causing, as is shown in Figure 3 (a) the wide diameter part 2a of inner tube 2 to be positioned within outer tube 1, blocking side holes 1a of outer tube 1 with the side wall of wide diameter part 2a.

In this way, it is possible to block from the inside the side holes 1a of outer tube 1 used for blood removal using the side wall of wide diameter part 2a of

inner tube 2 which is positioned within outer tub 1, thus making it possible to prevent with certainty the sanitary saline heparin solution in blood removal lumen 21 from escaping through side holes 1a, making it possible to maintain a heparin lock for an extended period of time. This makes it possible to prevent blood from flowing into blood removal lumen 21 by the escape of the sanitary saline heparin solution, making it possible to prevent situations where the blood removal flow is inadequate when circulation outside the body is restarted. Moreover, by equipping the tip portion of outer tube 1 with multiple side holes 1a, it is possible to increase the blood removal flow volume to increase the speed of circulation outside the body, thus making it possible to obtain an easily-used double catheter B that reduces the damage to the patient.

Form of Embodiment 3

Figure 4 shows a structural diagram of the third form of embodiment of this invention, where multiple side holes 2b blood supply through blood supply lumen 22 are equipped at in the side wall of the wide diameter part 2a of inner tube 2 of the first form of embodiment of this invention. Moreover, the inner diameter of the tip part of inner tube 2 (the lumen diameter of blood supply lumen 22) is structured in this form of embodiment with a size that is such that most of the sanitary saline heparin solution does not escape.

Even when structured in this way, the operation is the same as that explained for the first form of embodiment, where the double lumen catheter C is inserted into the blood vessel using a guide wire, etc., and is secured there (See Figure 4.) when in a state where the connection stop convex part 10a of the opening part side of position securing means 10 is stopped at the connection concave part 8b of position determination part 6. Then blood removal-side connector 5a and blood supply-side connector 11 are attached to their respective dialysis circuits, position securing means 10 is slid in the forward direction to cause the connection stop convex part 10b of the base part side of position securing means 10 to stop at the connection concave part 8b of position determination part 6, causing the wide diameter part 2a of inner tube 2 to extend out from the tip part of outer tube 1a to form a blood removal lumen tip op ning part 21a between the inner tube 2 and the tip part of outer tube 1. Moreover,

when th circulation outside of the body is started, blood flows into blood r moval lumen 21 through this blood removal lum n tip op ning part 21a and is delivered to the dialysis circuit while the blood from the dialysis circuit is delivered into the blood vessel through blood supply lumen 22 and its tip part and the side holes 2b.

After the circulation outside of the body is complete, then in the case where the double lumen catheter B will remain within the blood vessel, the blood removal-side connector 5a and blood supply-side connector 11 are removed from the dialysis circuit, blood removal lumen 21 and blood supply lumen 22 are flushed with the sanitary saline heparin solution, and a heparin lock is performed. Next the position securing means 10 is slid in the backwards direction to cause the connection stop convex part 10a of the opening part side of position securing means 10 to stop at the connection concave part 8b of the position determination part 6, causing, as is shown in Figure 4, the wide diameter part 2a of inner tube 2 to be positioned within outer tube 1, blocking the blood removal lumen tip opening part 21a, and blocking side holes 1a of outer tube 1 with the side wall of wide diameter part 2a.

In this way, it is not only possible to block the blood removal lumen tip opening part 21a with the wide diameter part 2a of inner tube a, that is located on the inside of outer tube 1, but it is also possible to block from the outside the side holes 2b of inner tube 2 used for blood removal, doing so with the side walls of the tip part of outer tube 1, and thus it is possible to stop with certainty the sanitary saline heparin solution within blood removal lumen 21 from escaping from blood removal lumen tip opening part 21a and to prevent with certainty the sanitary saline heparin solution with blood supply lumen 22 from escaping from side holes 2b, making it possible to maintain heparin locks in blood removal lumen 21 and blood supply lumen 22 for an extended period of time. This makes it possible to prevent blood from flowing into blood removal lumen 21 and blood supply lumen 22, thereby making it possible to obtain a high reliability double lumen catheter C that is able to prevent inadequate blood flow in the blood removal or blood supply when circulation outside of the body is restarted.

Form of Embodiment 4

Figure 5 shows a structural diagram of the 4th form of embodiment of this invention, where this form of embodiment not only has multiple side holes 1a for blood removal through blood removal 31 equipped in the tip part of outer tube 1, but also has multiple side holes 2b for blood supply through blood supply lumen 22 equipped in the side wall of wide diameter part 2a of inner tube 2. furthermore, when the wide diameter part 2a of inner tube 2 is positioned on the inside of outer tube 1, side holes 1a of outer tube 1 and side holes 2b of outer tube 2 do not line up with each other and thus side holes 1a and 2b are positioned such that side holes 2b and 1a are blocked by the side wall of the tip part of outer tube 1 and by the side wall of the wide diameter part 2a of inner tube 2, for example, the side holes 1a are positioned with a 90 degree offset from side holes 2b.

Even in the type of structure in this form of embodiment, the operation is the same as was explained in the first form of embodiment, where double lumen catheter D is inserted into a blood vessel using a guide wire, etc. and is secured there (See Figure 5) while the catheter is in a state where the connection stop convex part 10a of the opening part side of the position securing means 10 is stopped at connection concave part 8b of position determination part 6. Then the blood removal-side connection 5a and the blood supply-side connection 11 are connected to their respective dialysis circuits, position securing means 10 is slid in the forward direction to cause connection stop convex part 10b of the base part side of connection securing means 10 to stop at the connection concave part 8b of the position determination part 6, causing the wide diameter part 2a of inner tube 2 to protrude from the tip part of outer tube 1. At this time, the wide diameter part 2a of inner tube 2 does not protrude completely out of the tip part of outer tube 1, but rather the blood removal lumen tip opening part 21a is blocked by the wide diameter part 2a of inner tube 2 and the blood is removed only through the side holes 1a in outer tube 1. Moreover, when the circulation outside of the body is started, blood flows into blood removal lumen 21 through the side holes 1a in outer tube 1 and is sent to the dialysis circuit while blood from the dialysis circuit is delivered to the blood vessel through blood supply lumen 22 and from its tip part and from sid holes 2b.

After the circulation outside the body is complete, if double lumen catheter D is to be left inside the blood vessel, blood removal-side connector 5a and blood supply-side connector 11 are removed from the dialysis circuits, blood removal lumen and blood supply lumen 22 are flushed with sanitary saline heparin solution, and a heparin lock is performed. Then position securing means 10 is slid in the backwards direction to cause the connection stop convex part 10a of the opening part side of position determination means 10 to stop at the connection concave part 8b of the position determination part 6, and as shown in Figure 5, the wide diameter part 2a of inner tube 2 is caused to be positioned inside of outer tube 1 causing side holes 1a in outer tube 1 to be blocked by the side walls of the wide diameter part 2a, and causing side holes 2b in inner tube 2 to be blocked by the side walls of the tip portion of outer tube 1.

In this way it is possible to not only block from the inside the side holes 1a of outer tube 1 by the side walls of the wide diameter part 2a of inner tube 2, which is positioned on the inside of outer tube 1 during the heparin lock, but it is also possible to block the side holes 2b of inner tube 2 from the outside by the side walls of the tip portion of outer tube 1, thus making it possible to prevent with confidence and using simple operations the sanitary saline heparin solution from escaping through side holes 1a of outer tube 1 and through side holes 2b of inner tube 2, making it possible to maintain for an extended period of time the heparin lock of blood removal lumen 21 and blood supply lumen 22. By doing this, it is possible to prevent blood from flowing into blood removal lumen 21 and blood supply lumen 22 due to the sanitary saline heparin solution leaking out, thus making it possible to prevent situations where there is inadequate blood flow in the blood removal-side or the blood supply-side when circulation outside of the body is restarted, thus making it possible to obtain a double lumen catheter D that has high reliability and that places a low load on the doctor and on the patient. Furthermore, by equipping outer tube 1 and inner tube 2 with multiple side holes 1a and 2b it is possible to increase the blood removal and blood supply volume, thus increasing the speed of circulation outside of the body, making it possible to reduce the damage to the patient.

Form of Embodim nt 5

Figure 6 shows a structural diagram of the fifth form of embodiment of this invention. In this figure, 15 is a stylet that can be inserted into or removed from the blood supply lumen 22 of the inner tube 2 in the first form of embodiment of this invention, fitting in such a way as to cause a tight seal with at least the inner wall of the tip part of inner tube 2, where the outer diameter of this stylet is approximately the same as the inner diameter of tube 2 (the lumen diameter of blood supply lumen 22) where this inner diameter is approximately the same as the outer parameter of a guide wire 16 that is used when inserting the catheter into the blood vessel, and where the device is equipped with tubular main unit 15a the tip of which having a length that protrudes from the tip part of inner tube 2 and which has an outer diameter that is smaller at the tip, and has a connector 16c at one end, where plunger part 15b is equipped with a concave part 15b that fits into the base part of the blood supply-side connector 11 and is equipped with a connection stop part 15a that stops at flange part 11a of the blood supply-side connector at the inner peripheral surface at the other end, where the base part of the main unit 15a is affixed to the bottom of the concave part 15d of plunger part 15b so as to form a single unit. Moreover, the inner diameter of the tip part of inner tube 2 in this form of embodiment is constructed to be larger than the outer diameter if guide wire 16, where stylet 15 is fit into blood removal lumen 22 of inner tube 2 so as to block the gap between the inner wall of inner tube 2 and the outer wall of guide wire 16 that passes through blood supply lumen 22, not only preventing the stripping of the tip part of inner tube 2 when it is inserted into the blood vessel by eliminating the gap that appears between the tip portion of inner tube 2 and the guide wire 16, but reinforcing the hardness of the inner tube 2 and the entire double lumen catheter A.

In this form of embodiment of this invention, as is shown in Figure 6, first, while the catheter is in a state where the connection stop convex part 10a of the opening part side of the position securing means 10 is stopped at the connection concave part 8b of position determination part 6, the tip part of main unit 15 a of stylet 15 is inserted into blood supply lumen 22 of inner tube 2 of the double lumen catheter A through the blood supply-side connector 11 where stylet 15a is fitted into double lumen catheter A until position stop part 15e of plunger part

15b of stylet 15 is stopped at flange part 11a of blood supply-side connector 11, and guide wir 16, which has been insert d into the blood vessel is inserted into inner lumen 25 through the tip part of stylet 15. At this time, the tip part of the main unit 15a of stylet 15 extends out of the tip part of inner tube 2, and the main unit 15 forms a tight seal with at least the inside wall of the tip part of inner tube 2. Moreover guide wire 16, etc. is used to insert this double lumen catheter A into the blood vessel, where it is secured. At this time, the double lumen catheter A is inserted smoothly into the blood vessel with stylet 15 without the tip part of inner tube 2 being stripped.

Next, as guide wire 16 and stylet 15 are removed from inner lumen 25, stylet 15 is removed from double lumen catheter A, and blood removal-side connector 5a and blood supply connector 11 are connected to their respective dialysis circuits. Next position securing means 10 is slid, the wide diameter part 2a of inner tube 2 is caused to extend out of the tip part of outer tube 1, and the blood removal lumen tip opening part 21a is formed between the inner tube 2 and the tip portion of outer tube 1. Moreover, when the circulation outside of the body is started, blood flows into the blood removal lumen 21 from the blood removal lumen tip opening part 21a and is delivered to the dialysis circuit, while blood from the dialysis circuit is delivered into the blood vessel through blood supply lumen 22 from its tip part.

After the circulation outside of the body has been completed, then if the double lumen catheter A is to be left within the blood vessel, the blood removal side connector 5a and the blood supply side connector 11 are removed from the dialysis circuits, and a heparin lock is performed by flushing blood removal lumen 21 and blood supply lumen 22 with the sanitary saline heparin solution. Then the position securing means 10 is slid, the wide diameter part 2a of inner tube 2 is moved into outer tube 1, and the blood removal lumen tip opening part 21a is blocked by the wide diameter part 2a.

When double lumen catheter A, which has an inner tube 2 with an inner diameter that is bigger than the outer diameter of guide wire 16, is inserted into the blood vessel, stylet 15 is inserted into blood removal lumen 22 of inner tube 2 in order to block the gap b tween the inner wall of inner tube 2 and the outer wall of guide wir 16 and to cause the tip part of styl t 15 to protrude from the tip

part of inner tube 2, and thus it is possible to insert the double lumen catheter A into th blood v ssel smoothly, making it possible to reduce the damage to the patient. Moreover, because the insertion of stylet 15 reinforces the strength of double lumen catheter A as a whole, it is possible to insert double lumen catheter A with ease, without placing a strong force on the wall of the blood vessel by making it possible to follow a curved blood vessel, making it possible to obtain a double lumen catheter A with superior usability. Moreover, when a heparin lock is performed, because the blood removal lumen tip opening part 21a is blocked by the wide diameter part 2a of inner tube 2 that has been placed inside of outer tube 1, as it was in the first form of enablement, it is possible to maintain the heparin lock in blood removal lumen 21 for an extended period of time, and it is possible to prevent inadequate blood removal flow due to blood clots when blood circulation outside of the body is restarted. Moreover, in the form of enablement described above, the situation where a insertable and removable stylet 15 was fitted into blood removal lumen 22 of the inner tube of the first form of enablement, this invention could have been performed also in the forms of enablement 2 through 4 described above, or in the forms of enablement 6 and 7, described below with the same effects.

Form of Embodiment 6

Figure 7 is an expanded cross-sectional diagram of the important parts of the sixth form of enablement of this invention, where this form of enablement is one wherein the inner tube 2 of the first firm of enablement of this invention is formed from a 2-layer structure that has a material with hardness, such as polyimide, for example, with a surface 2c having a adhesive material, where the wide diameter part 2a is formed from a material with softness, such as, for example, a polyimide-system elastomer, where the tip part of this inner tube 2 is secured in the base part of the wide diameter part 2a so as to form a single unit. Moreover, the material that has the adhesive properties of the surface 2c has a compatibility with the material from which is constructed the wide diameter part 2a that is of superior adhesiveness. Moreover, wide diameter part 2a should be made from an elastic material.

By using this structure it is possible to obtain nearly the same operation

and effects as in the first form of embodiment, in preventing blood clots with blood removal lumen 21 from causing inadequate blood removal flow or from preventing the circulation at the time that circulation is restarted after an extended heparin lock of blood removal lumen 21, thus making it possible to reduce the load on the patient and on the doctor. Moreover, because the wide diameter part 2a of inner tube 2 was structured from a material that is soft or from an elastic material, when the wide diameter 2a is extended out from the outer tube 1, then no injury will be caused to the blood vessel even when the wide diameter part 2a comes in contact with the blood vessel wall, thus making it possible to obtain a high reliability double lumen catheter A. Moreover, because the inner tube 2 is formed from a material with hardness, it is possible to maintain the transmission of torque while suppressing the bending hardness of inner tube 2 even when the thickness of the side walls of inner tube 2 is made thinner through fabricating inner tube 2 with a large inner diameter in order to support a greater volume of blood flow through blood supply lumen 22, thus making it possible to obtain a double lumen catheter A with excellent usability.

Furthermore, while in the forms of embodiment described above, we have shown the situation where the inner tube 2 is constructed of materials which have excellent hardness, inner tube 2 can, for example, be made from materials that are relatively soft and thus are compatible with the large diameter part 2a and then, as shown in Figure 8, be strengthened by embedding into the walls of inner tube 2 a material such as, for example, the stainless steel wire web 17. Even in this case, the same results would be obtained. Furthermore, while this is shown in this particular embodiment of this invention using the inner tube 2 that is formed as found in the first example of embodiment of this invention, it may also be applied to the forms of embodiment of this invention found in the second through fifth examples described above, and in the seventh form of embodiment of this invention to be described below, and in these cases the results would be the same.

Form of Embodiment 7

Figure 9 shows a magnified cross-sectional diagram of the important parts of the seventh form of embodiment of this invention. In this form of embodiment at

l ast th tip-most part 18 of the tip inner tube 2 (i.e. the tip part of the wide diameter part 2a), which tube is equipped with side holes 2b as found in the third form of enablement of this invention, is blocked, where at the tip-most part of this tip part a horizontal or cross shaped slit 19 is provided to the blood removal lumen 22.

Using this structure the same operation and results can be obtained as in the third form of embodiment of the invention, where the load on the patient and on the doctor can be reduced by preventing inadequate blood removal and blood supply flow volumes (due to blood clots in the blood removal lumen 21 and the blood supply lumen 22 after circulation outside the body is restarted after a heparin lock is maintained in blood removal lumen 21 and blood supply lumen 22 for an extended period of time. Moreover, although the tip-most part 18 of inner tube 2 is fabricated so that it is closed, because slit 19 is provided, guide wire 19, which is used when equipping double lumen catheter C into the blood vessel, can be received easily, and by closing the tip-most part 18 it is possible to maintain a heparin lock while preventing blood from flowing into blood removal lumen 22 and preventing the sanitary saline heparin solution from escaping from the tip of blood removal lumen 22.

Furthermore, as was shown in the example and explained in the embodiment of this invention where inner tube 2 of the double lumen catheter C in the third form of embodiment of this invention described above can also be applied in the fourth form of embodiment of this invention with equal effectiveness.

While several forms of embodiment of this invention have been described above, this invention is not limited to these particular forms; for example, it would be appropriate to perform the changes described below:

(1) In the first form of embodiment, while, as shown in Figure 10 (a) the outer radius of the tip part R1 of outer tube 1 was shown with a reduced radius (r1), however, as shown in Figure 10 (b) the inner radius R2 may also be set at a reduced radius (r2) to insure a firm contact with the side walls of wid diameter part 2a of inner tube 2, and, as shown in Figure 10 © the tip portion may be made

from an elastic material 20, and th outer diameter and inner diameter may b reduced to insure a solid seal with the wid diameter portion 2a of inner tube 2. Moreover, this invention may be applied to not only the first form of embodiment of this invention, but to the second to seventh forms of embodiment of this invention as well, with equal effectiveness in these cases.

(2) In the second and fourth forms of embodiment of this invention, a situation was shown where the wide diameter part 2a of inner tube 2 did not extend completely from the outer tube 1, and instead the blood removal was performed only through side holes 1a in outer tube 1 because the blood removal lumen tip opening part 21a was blocked by the wide diameter part 2a of inner tube 2; however, the blood removal could also be through both the blood removal lumen tip opening part 21a and the side hole 1a by causing the wide diameter part 2a of inner tube 2 to completely extend out from the outer tube 1, as shown, for example, in the first form of embodiment of this invention. In this case, it would be possible to increase the flow of blood removed and thus increase the speed of circulation outside the body.

(3) It is also acceptable to lubricate, with, for example, silicon oil, the inner wall of the outer tube 1 and/or the outer wall of the wide diameter part 2a of inner tube 2 in order to increase the slidability of the movement of inner tube 2, and thus improve the ease of use of the double lumen catheter. Moreover, the outer wall of stylet 15 and/or the inner wall of inner tube 2 may also be lubricated to improve the ease of sliding motion of stylet 15.

(4) Moreover, the support tube 3 affixed in outer tube 1 may be liminat d, the blood removal tube 3c may branch near the base part of outer tube 1 or the blood removal tube 3c may branch at an angle.

As described ab ve, the double lumen cath t r of this invention is equipped with a double lumen catheter characterized by at least a double lumen formed from a blood removal lumen, which is a lumen that is formed between an outer tube, wherein the tip part outer radius is reduced, and an inner tube, wherein the outer diameter of the inner tube is smaller than the inner diameter of the aforementioned outer tube, and where the tip portion of the inner tube is equipped with a wide diameter part wherein the outer diameter of the tip part of the inner tube is nearly the same as the inner diameter of the tip part of the outer tube, and a blood delivery lumen, which is the inner lumen of the inner tube, where the blood removal lumen is equipped with a blood removal tube that extends in a branch from the blood removal lumen near the base of the outer tube, and equipped with a seal valve unit that seals the blood removal lumen at the base side near the branch part of the outer tube and that can cause the inner tube to slide freely, and by being equipped with a freely constricting sleeve that tightly covers and seals the inner tube and which is located within the position securing means between base inner side of the position securing means and the base of the position determination means along with having a position securing means that is nearly tube shaped and which is equipped with connect stop parts in at least 2 locations on the inner peripheral surface and that are formed as a single unit at one end of a blood delivery-side connector where the blood delivery-side connector is equipped at the base part of the inner tube, and a position-determination part that slides freely within the position-securing means and which can slide freely into the inner tube, and which is equipped with a connection part stopped by the connection stop part of the position securing means at the outer peripheral surface, not only does the wide diameter part extend from the outer tube part to for a blood removal lumen tip opening part between the inner tube and the tip part of the outer tube when the connection part of the position determination materials is stopped at the connection stop part of the position securing means but also the side diameter part is located within the outer tube, which blocks the blood removal lumen tip opening part when the connection part of the position determination part is stopped at the connection stop part that is equipped in the opening part side of the other end of the position

securing means, and thus with this structure it is possible to use a simple structure to asily open and close the blood removal lumen tip opening part, making it possible to maintain a heparin lock with confidence over an extended period of time when the double lumen catheter is left within the blood vessel. Through this process, it is possible to prevent blood clots from causing inadequate blood removal flow or from preventing circulation when the circulation outside of the body is restarted, thus not only making it easy to restart circulation outside the body but also making it possible to eliminate the need to replace with a new catheter when restarting the circulation outside of the body, thus relieving the load on the patient and on the doctor, and making it possible to obtain a double lumen catheter that has excellent ease and economy of use.

Moreover, the double lumen catheter of this invention is one wherein the side wall of the tip part of the outer tube and/or the side wall of the wide diameter part being equipped with at least one side hole, and structured so that when th wide diameter part is positioned within the outer tube, the side holes in the outer tube tip part and/or the side holes in the wide diameter part are positioned so that the side wall of the outer tube and/or the side wall of the wide diameter part block the side holes, and structured so that when the connector part of the position determination part is positioned at the stop part at the base side of the position securing means, then the wide diameter part extends from the outer tube and a blood removal tip opening is formed between the inner tube and the outer tube tip part, or the wide diameter part opens the outer tube tip part side holes and wide diameter part high side holes without extending out of the outer tube, and when the position determination means connection part is stopped at the stop part equipped on the opening side of the position securing means, the wide diameter part blocks the outer tube side holes and the wide diameter part side holes and the blood removal lumen tip opening part, and thus it is not only possible to prevent with certainty blood clots from prevent circulation, doing so by closing off with certainty the blood removal lumen tip opening part and closing off the side holes when performing a heparin lock, but it is also possible to provide multiple side holes to increase the blood removal flow and the blood deliv ry flow, making it possible to increase the rat of circulation outsid of th body, thus reducing the damage on the patient and making it possible to obtain a

double lumen catheter with superior ease of use.

The double lumen catheter of this invention is equipped with a stylet, which is equipped with a plunger at its base, which can easily fit into the blood delivery lumen of the inner tube so that the tip part extends from the tip part of the outer tube and its outer wall forms a tight seal with at least the inner wall of the tip part of the inner tube, making it not only possible to prevent peeling during the insertion into the blood vessel of the tip part of the inner tube when the inner tube has a large inner diameter in its tip part, but it also makes it possible to reinforce the strength of the double lumen catheter as a whole to facilitate smooth insertion into the blood vessel, thus making it possible to obtain a double lumen catheter with superior ease of use that reduces the load on both the doctor and the patient.

The double lumen catheter of this invention is one which is structured so that the inner diameter of the tip part of the outer tube is of an smaller diameter, or so that the reduced diameter part is made from elastic materials, making it possible to increase the seal with the wide diameter part of the inner tube, making it possible to prevent with certainty problems with inadequate blood removal flow or the inability to circulate the blood due to blood clots.

The double lumen catheter of this invention is one which wherein the inner walls of the inner tube being structured from materials that are hard whil along with the outer wall of the inner tube being structured from materials that have relatively good compatibility with the wide diameter part where the inner tube is structured in an outer wall and inner wall double-layer structure such that the large diameter part is made from a soft material, or structured with metal wires being embedded within the inner wall of the inner tube, or structured with the wide diameter part being structured from an elastic material, making it possible to not only reduce the risk of damaging the walls of the blood vessel, etc., through the protrusion of the wide diameter part from the outer tube, but also to reduce the hardness of the of the inner tube while yet maintaining its ability to transmit torque, thus making it possible to obtain a high-reliability double lumen catheter with superior ease of us .

The doubl lumen catheter of this invention is equipped with a slit at the tip of the inner tube, where the tip of the inner tube is structured in a form where

the most leading edge of the tip is blocked, thus making it possibl to prevent with certainty the flow of blood into the blood r moval lumen, and to prev nt with certainty the escape of the sanitary saline heparin solution from the blood removal lumen without interfering the operation involved in placing the catheter into the blood vessel.

DOUBLE LUMEN CATHETER

CLAIMS

1. A double lumen catheter characterized by at least a double lumen formed from a blood removal lumen (21), which is a lumen that is formed between an outer tube (1), wherein the tip part outer radius is reduced, and an inner tube (2), wherein the outer diameter of said inner tube (2) is smaller than the inner diameter of the aforementioned outer tube (1), and where the tip portion (2a) of said inner tube (2) is equipped with a wide diameter part (2a) wherein the outer diameter of said tip portion (2a) of said inner tube (2) is nearly the same as the inner diameter of the tip part of said outer tube (1), and a blood delivery lumen (22), which is the inner lumen of said inner tube (2), where the blood removal lumen (21) is equipped with a blood removal tube (3c) that extends in a branch from said blood removal lumen (21) near the base of said outer tube (1), and equipped with a seal valve unit (9) that seals said blood removal lumen (21) at the base side near the branch part of said outer tube (1) and that can cause said inner tube (2) to slide freely.

2. The double lumen catheter of Patent Claim 1 characterized by being equipped with a freely constricting sleeve (13) that tightly covers and seals the inner tube (2) and which is located within said position securing part (10) between base part side of said position securing part (10) and the base of said position determination part (6) along with having a position securing part (10) that is nearly tube shaped and which is equipped with connect stop parts (10a, 10b) in at least two locations on the inner peripheral surface which are formed as a single unit at one end of a blood delivery-side connector (11) where said blood delivery-side connector (11) is equipped at the base part of the inner tube (2), and a position determination part (6) that slides freely within the position-securing part (10) and which can slide freely into said inner tube (2), and which is equipped with a connection part (8b) stopped by the connection stop part (10a, 10b) of said position securing part (10) at the outer peripheral surface.

3. The double lumen cath ter of Patent Claim 2 characterized by being structured so that the blood r moval lumen tip opening part (21a) formed between the inner tube (2) and the outer tube tip part (1) by the wide diameter part (2a) extending out from said outer tube (1) when the connection part position determination part is stopped at the connection stop part (15e) equipped on the base side of the position securing part, and said wide diameter part blocks said blood removal lumen tip opening part (21a) by being placed in said outer tube (1) when said position determination part (6) of the connection part is stopped at the connection stop part (15a) that is equipped at the opening part side at the other end of said position securing part (10).

4. The double lumen catheter of Patent Claim 2 characterized by the side wall of the tip part of the outer tube (1) and/or the side wall of the wide diameter part being equipped with at least one side hole (1a), and structured so that when said wide diameter part (2a) is positioned within said outer tube (1), said side holes (1a) in said outer tube tip part (1) and/or the side holes (2b) in said wide diameter part (2a) are positioned so that the side wall of said outer tube (1) and/or the side wall of said wide diameter part (2a) block said side holes (2b), and structured so that when the connector part of said position determination part (6) is positioned at the stop part at the base side of the position securing part (10), then said wide diameter part (2a) extends from said outer tube (1) and a blood removal tip opening is formed between the inner tube (2) and the outer tube tip part, or said wide diameter part (2a) opens said outer tube tip part side holes and wide diameter part high side holes without extending out of said outer tube, and when the position determination part (6) connection part is stopped at the stop part equipped on the opening side of said position securing part (6), said wide diameter part (2a) blocks the outer tube side holes (1b) and the wide diameter part side holes (2b) and said blood removal lumen tip opening part (21a).

5. Th double lumen catheter of Patent Claims 1, 2, 3, or 4, characterized by being equipped with a stylet (15), which is equipped with a plunger (15b) at its base, that can easily fit into the blood delivery lumen (22) of the inner tube (2) so that the tip part extends from the tip part of said outer tube (1) and its outer wall forms a tight seal with at least the inner wall of the tip part (2a) of the inner tube (2).

6. The double lumen catheter of Patent Claims 1, 2, 3, 4, or 5, characterized by being structured so that the inner diameter of the tip part of the outer tube (1) is of an smaller diameter, or so that said reduced diameter part is made from elastic materials.

7. The double lumen catheter of Patent Claims 1, 2, 3, 4, 5, or 6 characterized by the inner walls of said inner tube (2) being structured from materials that are hard while along with the outer wall of said inner tube (2) being structured from materials that have relatively good compatibility with said wide diameter part (2a) where the inner tube is structured in an outer wall and inner wall double-layer structure such that the large diameter part is made from a soft material.

8. The double lumen catheter of Patent Claims 1, 2, 3, 4, 5, 6, or 7 characterized by metal wires (17) being embedded within the inner wall of the inner tube.

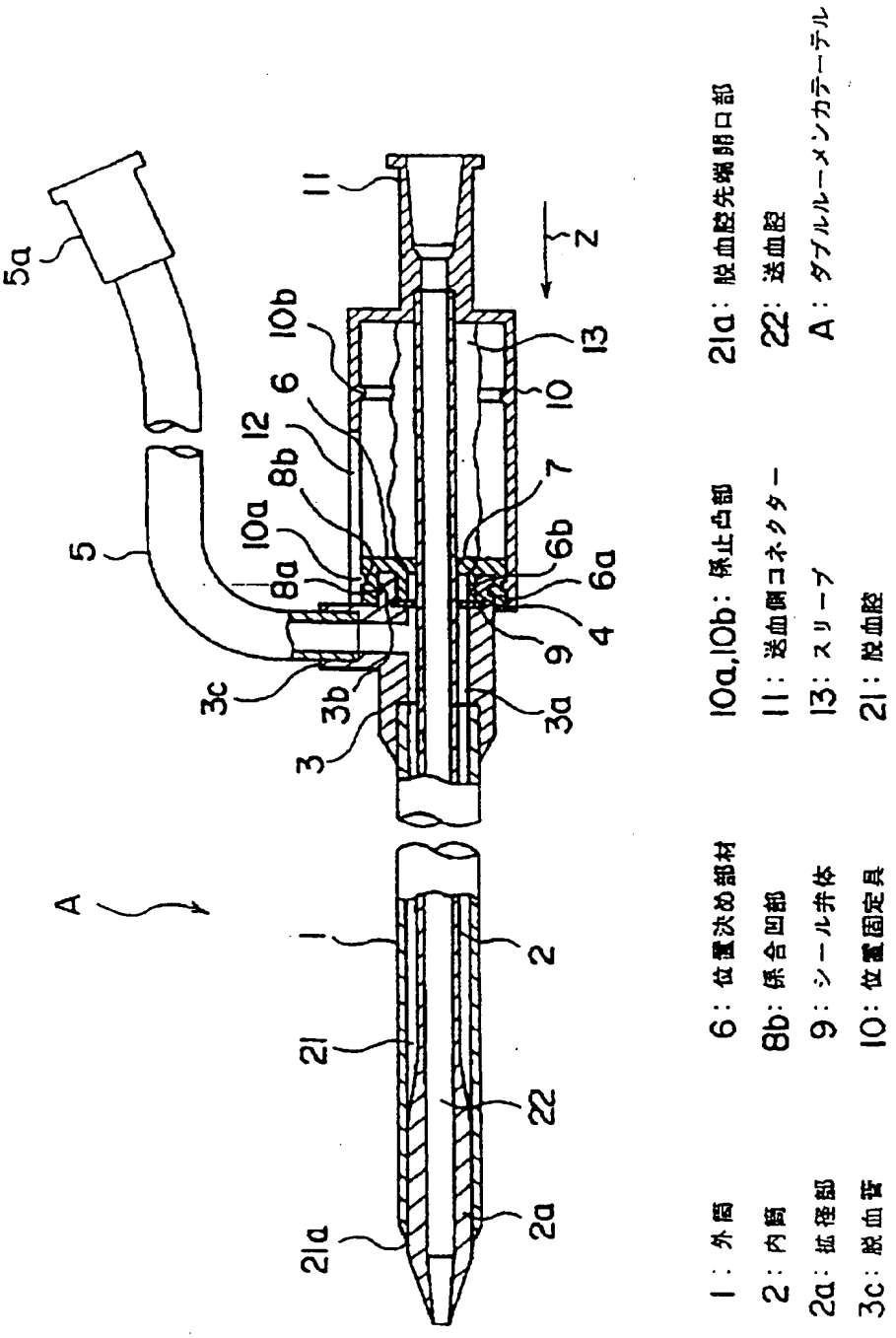
9. The double lumen catheter of Patent Claims 1, 2, 3, 4, 5, 6, 7, or 8 characterized by the wide diameter part being structured from an elastic material.

10. The double lumen catheter of Patent Claims 1, 2, 3, 4, 5, 6, 7, 8, or 9 characterized by being equipped with a slit (19) at the tip of said inner tube (2), where the tip of th inner tube (2a) is structured in a form where the most leading edge of th tip is block d.

整理番号＝ＰＪ６１５０　　ページ（　１／　９）

【書類名】　図面

【図１】



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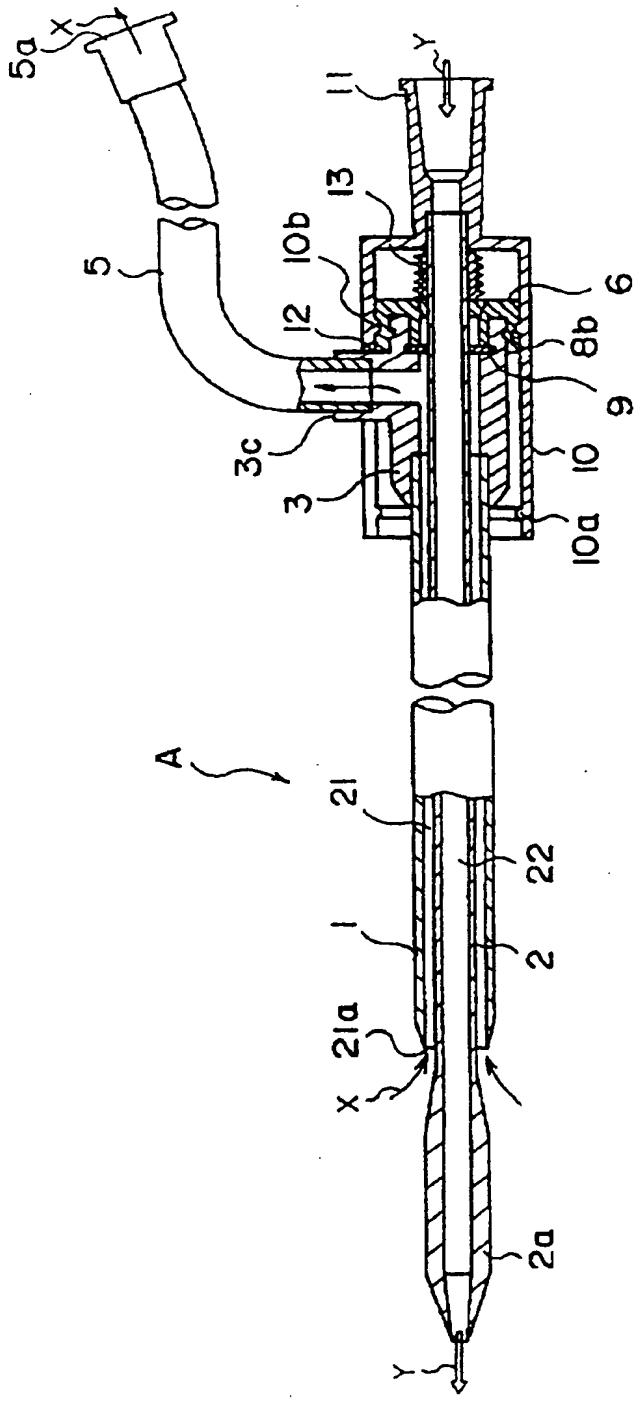
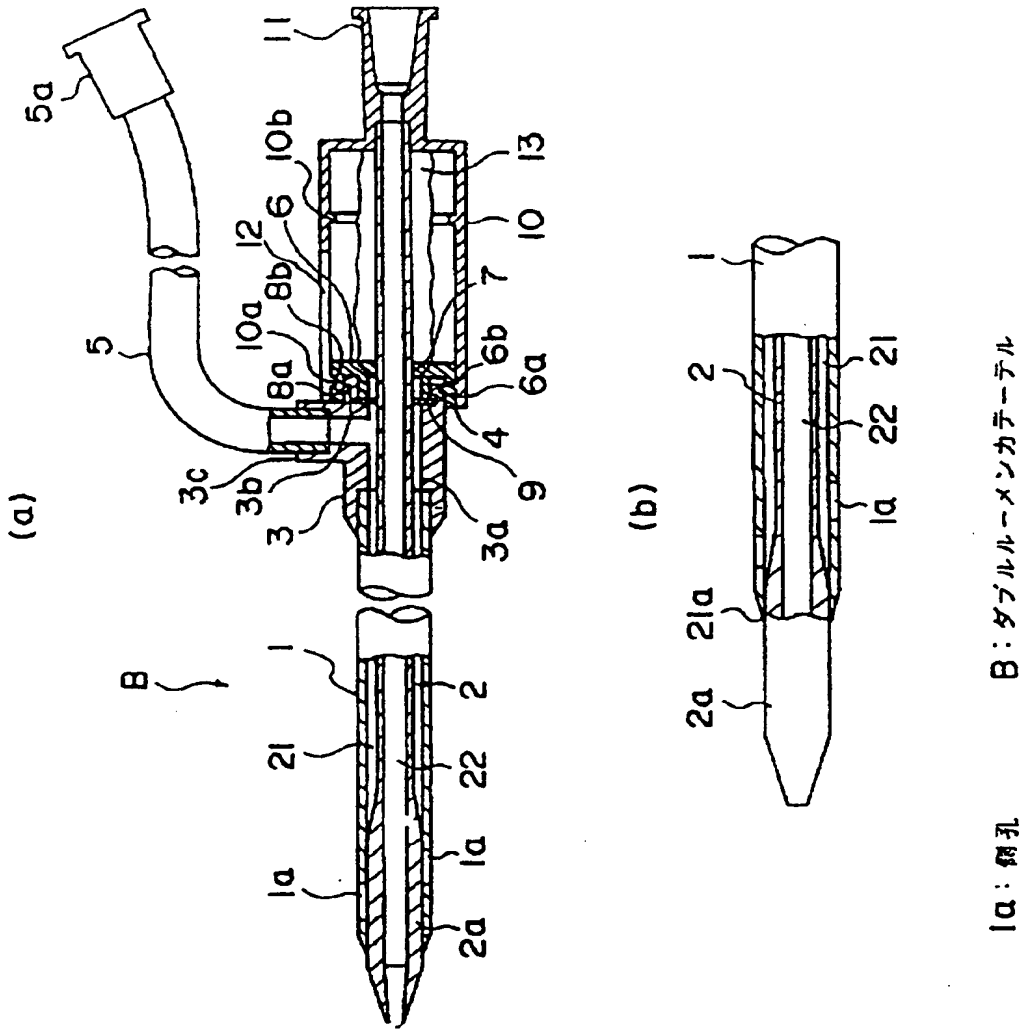
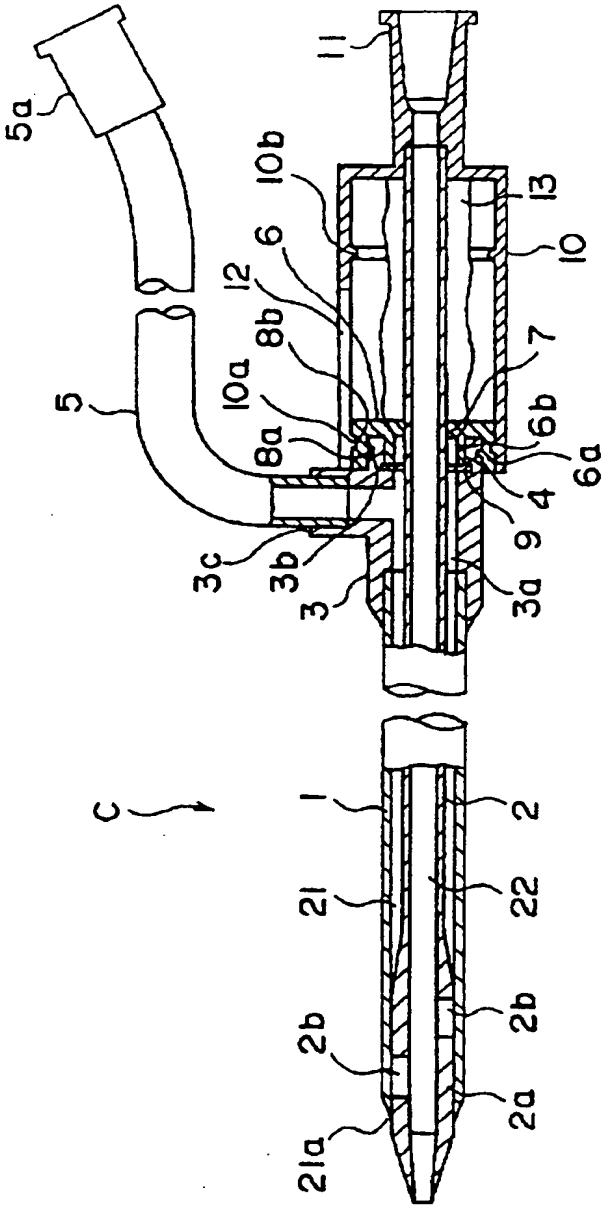


整理番号＝ＰＪ６１５０ ページ（ 3／ 9）

【図３】



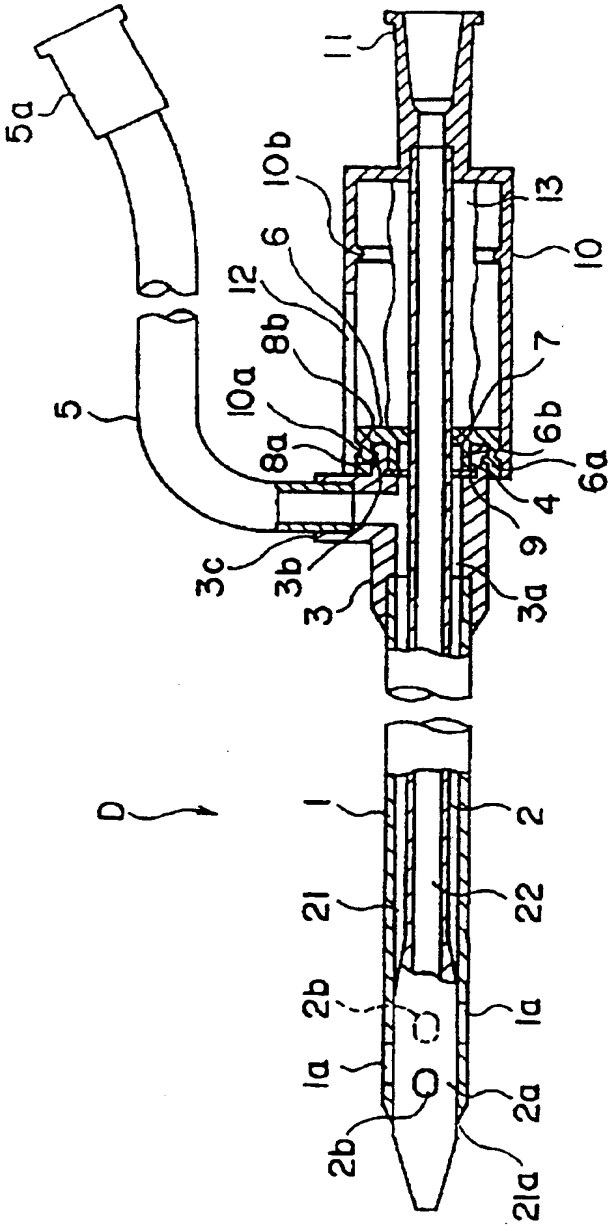
【図４】



C：ダブルルーメンカテーテル

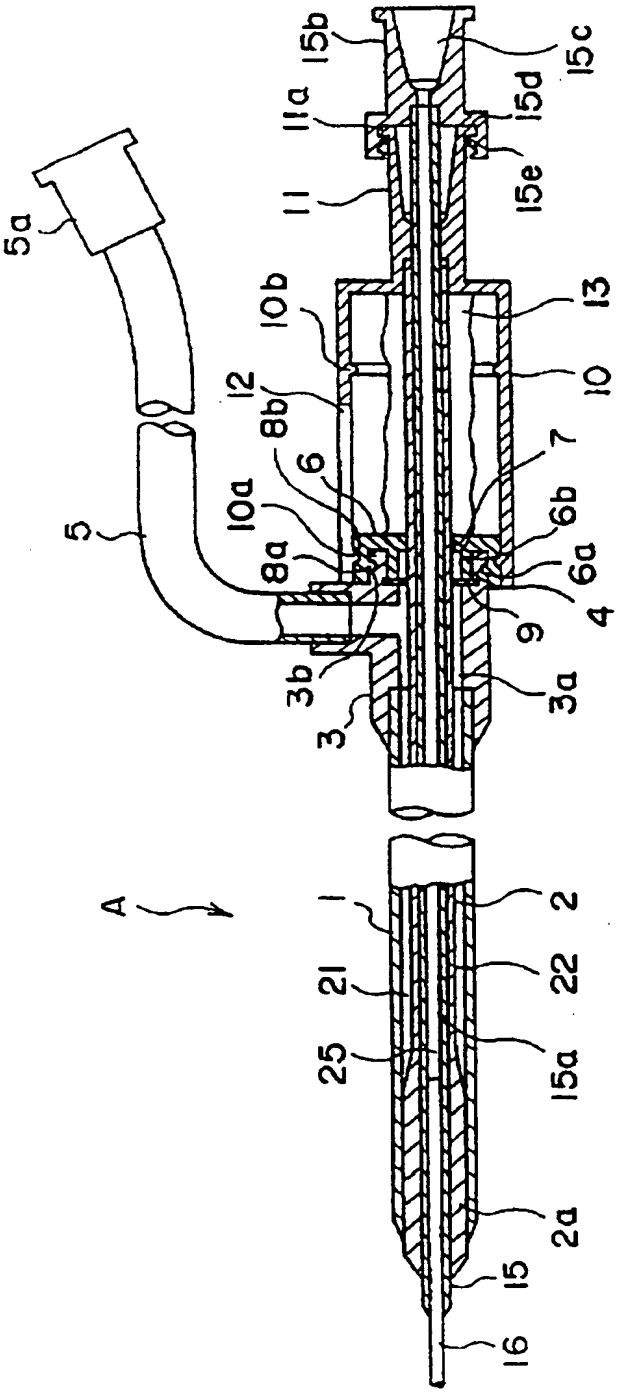
2b：側孔

【図５】



D：ダブルルーメンカテーテル

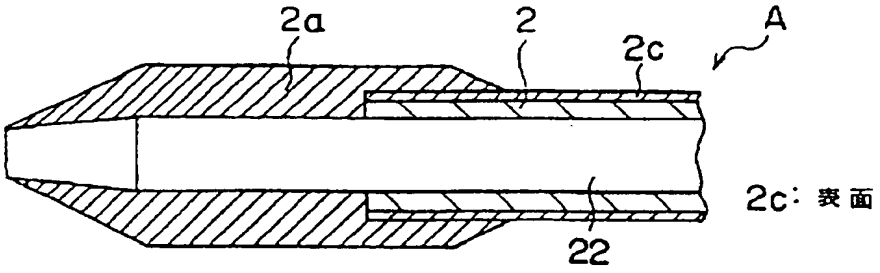
【図６】



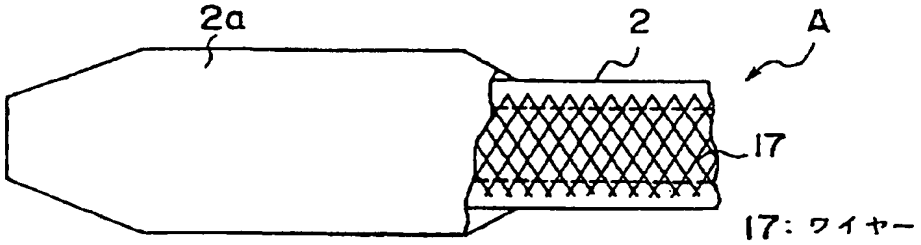
15：スタイレット　15b：嵌合部　15e：係止部

15a：本体

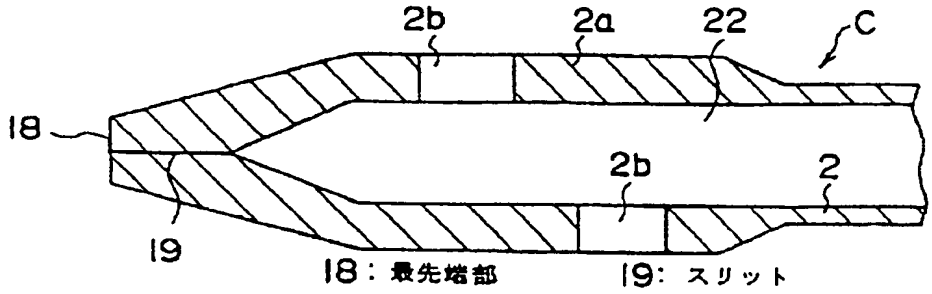
【図７】


2a
2
2c
A
2c：表面
22

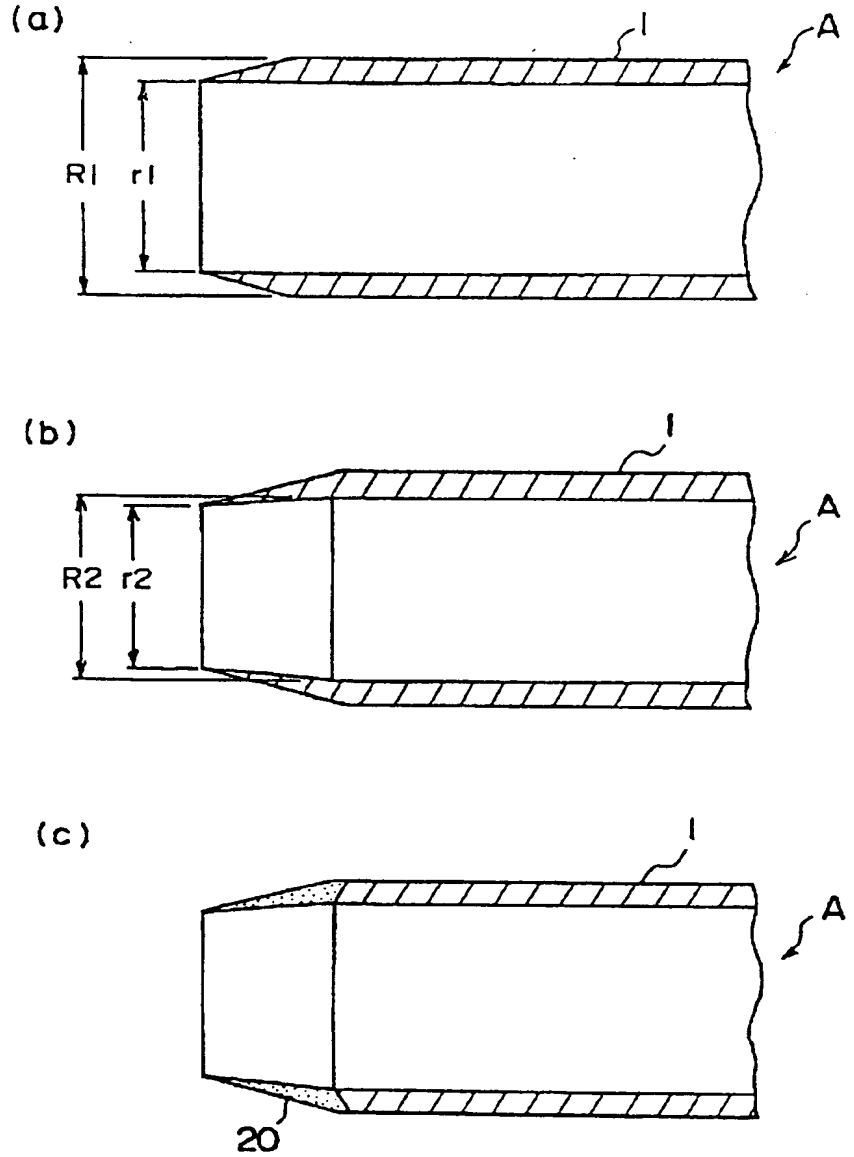
【図８】


2a
2
A
17
17：ワイヤー

【図９】

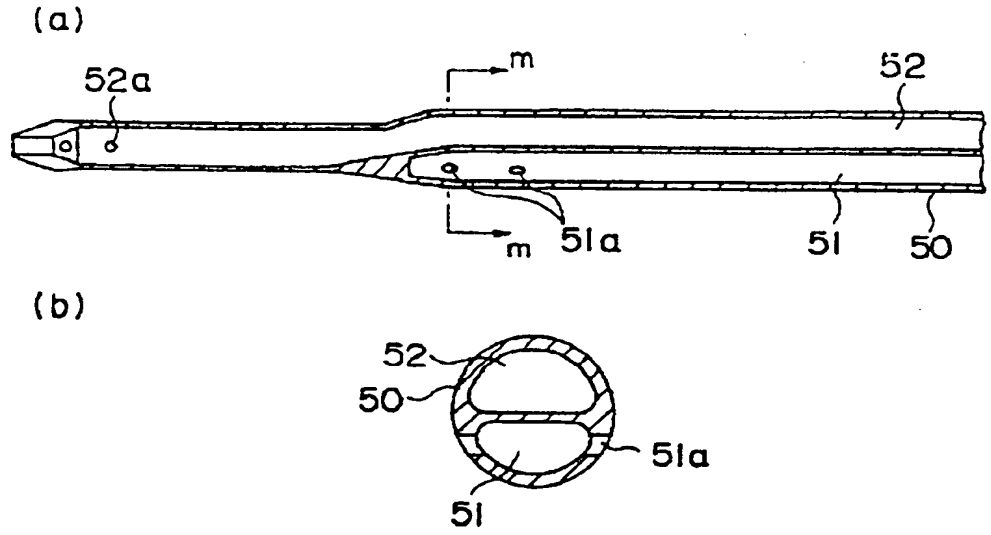

2b
2a
22
C
18
2b
2
19
18：最先端部
19：スリット

【図１０】

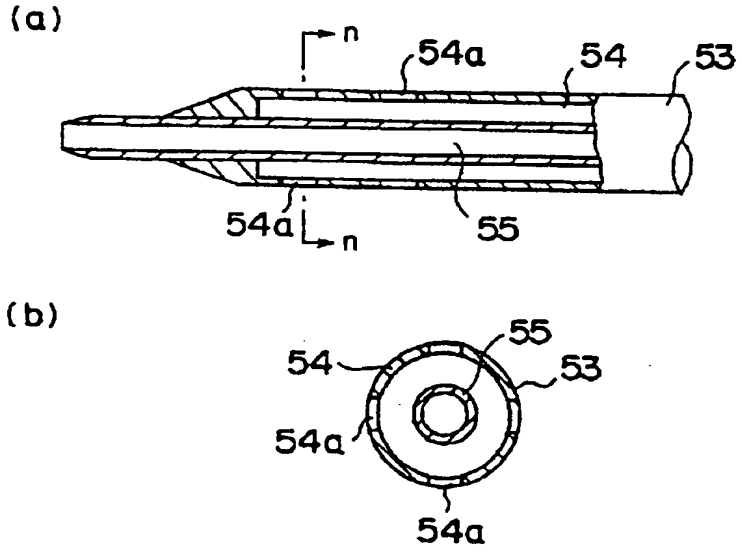


20：弾性部材

【図１１】


(a)
52a
m
52
m
51a
51
50
(b)
52
50
51a
51

【図１２】


(a)
n
54a
54
53
54a
n
55
(b)
55
54
53
54a
54a

INTERNATIONAL SEARCH REPORT

International application No.
PCT/US97/04885

A. CLASSIFICATION OF SUBJECT MATTER
IPC(6) :A61M 3/00, 3/02, 25/00
US CL :604/40, 43, 285
According to International Patent Classification (IPC) or to both national classification and IPC

B. FIELDS SEARCHED

Minimum documentation searched (classification system followed by classification symbols)
U.S. : 604/40, 43, 285, 4, 27, 30, 35, 36, 39, 42, 164, 165, 167, 169, 170, 264, 280, 283

Documentation searched other than minimum documentation to the extent that such documents are included in the fields searched
NONE

Electronic data base consulted during the international search (name of data base and, where practicable, search terms used)
APS

C. DOCUMENTS CONSIDERED TO BE RELEVANT

Category*	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
X -- Y	US 2,148,541 A (DIERKER) 28 February 1939, see figures 2 and 5.	1, 6, 9, 10 --- 1,5,6,8-10
X	US 1,494,344 A (DEBEN) 20 May 1924, see figure 1.	1, 6, 9, 10
Y	US 5,437,673 A (BAUST et al) 01 August 1995, see entire document.	1, 5, 6, 8-10
Y	US 5,176,660 A (TRUCKAI) 05 January 1993, see figure 5.	8
Y	US 4,004,588 A (ALEXANDER) 25 January 1977, see figure 4.	5

[X] Further documents are listed in the continuation of Box C. [ ] See patent family annex.

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"O" document referring to an oral disclosure, use, exhibition or other means
"P" document published prior to the international filing date but later than the priority date claimed
"T" later document published after the international filing date or priority date and not in conflict with the application but cited to understand the principle or theory underlying the invention
"X" document of particular relevance; the claimed invention cannot be considered novel or cannot be considered to involve an inventive step when the document is taken alone
"Y" document of particular relevance; the claimed invention cannot be considered to involve an inventive step when the document is combined with one or more other such documents, such combination being obvious to a person skilled in the art
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Date of the actual completion of the international search
11 JUNE 1997

Date of mailing of the international search report
08 JUL 1997

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INTERNATIONAL SEARCH REPORT

International application No.
PCT/US97/04885

C (Continuation). DOCUMENTS CONSIDERED TO BE RELEVANT

Category*	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
A	US 4,014,333 A (MCINTYRE) 29 March 1977, see entire document.	3, 4
A	US 4,648,865 A (AIGNER) 10 March 1987, see entire document.	3, 4
A	US 5,053,004 A (MARKEL et al) 01 October 1991, see entire document.	1-10